

2738. Adulteration of sodium sulfadiazine solution. U. S. v. 125 Ampuls * * *.
(F. D. C. No. 26019. Sample No. 1319-K.)

LIBEL FILED: On or about November 16, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: Between the approximate dates of April 2, 1947, and March 31, 1948, from Indianapolis, Ind.

PRODUCT: 125 20-cc. ampuls of *sodium sulfadiazine solution* at Atlanta, Ga.

LABEL, IN PART: "Ampul Solution Sodium Sulfadiazine 25% W/V * * *
Use only intravenously."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it was represented to possess since it was represented for intravenous use and was contaminated with undissolved material, whereas an article represented for intravenous use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 10, 1948. Default decree of condemnation and destruction.

2739. Adulteration of Bromsulphalein. U. S. v. 20 Boxes * * *. (F. D. C. No. 26901. Sample No. 57795-K.)

LIBEL FILED: April 4, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about December 28, 1948, by Hynson, Westcott & Dunning, Inc., from Baltimore, Md.

PRODUCT: 20 boxes of *Bromsulphalein* at Wilmington, Calif.

LABEL, IN PART: (Box) "Ten Ampules 3-cc. Size Bromsulphalein (H. W. & D. Brand of Sulfobromophthalein Sodium U. S. P. * * *) Sterile 5% Aqueous Solution Lot No. 335."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as a drug, "Sulfobromophthalein Sodium Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: May 16, 1949. Default decree of condemnation and destruction.

2740. Adulteration and misbranding of estrogenic substance. U. S. v. 91 Vials * * *. (F. D. C. No. 26555. Sample No. 15268-K.)

LIBEL FILED: March 7, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 11, 1948, by the Estro Chemical Co., from New York, N. Y.

PRODUCT: 91 10-cc. vials of *estrogenic substance* at Chicago, Ill.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * (Estrogenic Substances predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to an article which contained materially less than 97 percent of